# Measuring Psychotropic Drug Effects and Side Effects


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## Introduction

The treatment of challenging behaviors and mental illness in persons with autism spectrum disorder (ASD) or other pervasive developmental disorders (PDD) frequently includes psychotropic medications that necessitate monitoring for medication effects and side effects. It is well-established that the treatment plans of more than 50% of people with ASD include psychotropic medications (Houghton et al., 2017; Jobski et al., 2017; Madden et al., 2017; Vohra et al., 2016). Persons with ASD are commonly treated with multiple medications, with polypharmacy occurring at triple the rate of non-ASD populations (Vohra et al., 2016). Polypharmacy brings risk of drug interactions and increased medication side effects in a population known to experience an increased incidence of medication side effects at baseline. The increased incidence of side effects has been attributed to multimorbidity in combination with high doses of medication administered over longer periods of time (Ji & Findling, 2016; Matson & Mahan, 2010a, 2010b; O'Dwyer et al., 2016. Nearly a decade ago, Matson and Hess (2011) cited the need for establishing psychopharmacological best practices for persons with ASD in order to minimize risks, yet best practices for measuring the effects of medication and monitoring for side effects are still evolving.

Obstacles to medication monitoring must be addressed to ensure quality patient care. Provider obstacles include limited experience treating persons with ASD/PDD, communication skills, and lack of knowledge regarding best practices for medication management, such as the use of standardized measures (Bakker-van

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Gijssel et al., 2017; Matson & Neal, 2009). Patient specific challenges include multimorbidity, expressive and receptive communication disorders, unique sensory awareness, barriers to completing forms, and multiple carers (Brookman-Frazee et al., 2017; Kohane et al., 2012; Turygin et al., 2014). Care systems also impact quality of care and the implementation of standardized measures. Care systems must support the measurement of medication effects and side effects though the provision of time, access to measurement scales, and staff and carer training (Bakker-van Gijssel et al., 2017). Addressing the barriers to medication monitoring is necessary to ensure quality mental healthcare and minimize carer and provider burnout.

## Overview of the Measurement of Psychotropic Medication Effects and Side Effects

All ingested substances have effects on the body. The psychotropic medications prescribed to ameliorate symptoms of mental illness are no exception and can lead to dramatic improvement, but also unwanted outcomes. As this chapter explores the effects and side effects of psychotropic medication, *effect* will refer to the effectiveness of medication in producing a desired outcome, such as ameliorating target symptoms. Measuring the effect of medication is part of progress monitoring. While medications are prescribed to elicit a specific desired benefit or effect, all medications come with risk of harm. Medical literature lacks standardized terminology for the harm caused by medication (Falconer et al., 2019). This chapter will use *side effect* to denote an undesirable consequence of a medication that is a known risk, such as those listed as adverse reactions in the *Physician's Desk Reference*.

The best practice is evolving for measuring the effects and side effects of medication in persons with ASD/PDD. Professional medical organizations, the U.S. Food and Drug Administration, the National Institute for Medical Care and Excellence (NICE), and others publish guidance for prescribers of psychotropic medications, but there are limited publications addressing the medication needs of persons with ASD/PDD. The American Academy of Child and Adolescent Psychiatry (AACAP) has issued *Practice Parameters* specific to youth with ASD (Volkmar et al., 2014) and ID (Siegel et al., 2020). The British Association for Psychopharmacology has issued consensus guidelines which address the treatment of persons with ASD (Howes et al., 2018). The World Psychiatric Association (Deb et al., 2009), NICE (2017), and The *Frith Guidelines* (Bhaumik et al., 2015) offer guidance for prescribing to persons with intellectual disability (ID). Guidelines universally note the importance of "starting low and going slow" when prescribing medication for persons with ASD/PDD, as there is an increased risk for side effects due to neurophysiological vulnerability (Grier et al., 2018). While monotherapy is preferred, polypharmacy may be unavoidable and requires that medications be started sequentially whenever possible (Deb et al., 2009). As medication changes are made,

treatment or habilitation plans must be updated. When medications are discontinued, thought must be given to deprescribing carefully in order to avoid unwanted side effects including seizures, abnormal movements, sleep disturbance, and flu-like symptoms (Farrell & Mangin, 2019; Ostrow et al., 2017). In recognition of the risks of over-prescribing and polypharmacy, the Stop Overmedication of People with ID, autism, or both (STOMP) program has been developed to promote medication reduction and deprescribing (Branford et al., 2019). Guidelines for deprescribing are available on the STOMP professional resources webpage.

## Monitoring Instruments

The *Diagnostic and Statistical Manual of Mental Disorders* (*DSM 5*) provides the basis for diagnosing mental illness and monitoring treatment efficacy. The *DSM 5* is a nosological, categorical system of classifying mental illness by symptom constellation rather than disease etiology. This approach allows for limited therapeutic personalization and may fail to capture complex clinical presentations. If routine behavioral or psychosocial approaches fail to ameliorate mental illness or challenging behaviors, a functional behavioral assessment (FBA) and medical evaluation should be considered before medication is prescribed (Howes et al., 2018). Since individuals with ASD usually fit criteria for multiple mental disorders, an FBA is useful to systematically identify the function or purpose of a behavior and the factors which trigger and maintain the behavior. The prudent clinician will document the target symptoms that each medication treats and track progress monitoring with an FBA or standardized instruments (Valdovinos et al., 2016).

A medical evaluation prior to starting psychotropic medication is necessary to identify physical illness that may be presenting as mental illness or a challenging behavior and to establish a baseline for pre-existing medical conditions with symptoms that might later masquerade as a side effect (Howes et al., 2018; Trollor et al., 2016). Seizure disorders, gastrointestinal issues, obesity, immune disorders, hypertension, and diabetes are among the illnesses more common in persons with ASD/PDD than in the general population (Cooper et al., 2015; Croen et al., 2015). For persons with co-morbid seizures or cardiac abnormalities, clinicians should consider consultation with a medical specialist (Bhatti et al., 2017; Ko, 2015). Multimorbidity increases the complexity of psychotropic medication monitoring and may require collaboration across disciplines which is best accomplished in a medical home (Todorow et al., 2018). Medication-specific requirements may also include laboratory studies and electrocardiography (EKG) in addition to routine vital signs. Because of individual treatment responsiveness to medication pharmacokinetics, pharmacogenetic testing may be indicated in some persons (Bousman et al., 2019). Lastly, a person's age, gender, ethnicity, genetics, health status, and use of alcohol or tobacco may influence the presentation of side effects.

## The Measurement of Psychotropic Medication Effects and Side Effects

Numerous instruments have been developed to inform clinical judgment in prescribing medication (Chang et al., 2014; Matson & Mahan, 2010a, 2010b; Stomski et al., 2015; van Strien et al., 2015), but few have been well-studied in persons with ASD/PDD (McConachie et al., 2015) (see Table 1). While general inquiry by the prescriber or treatment as usual (TAU) is the most common monitoring method, drug-specific checklists and scales are necessary for research and support improved patient outcomes and cost-effective care by promoting the early identification of side effects and allowing the treatment team to alter course when effects are not forthcoming (Coates et al., 2018). Large-scale studies documenting the benefits of medication-specific monitoring have targeted adults through online and nurse-administered instruments and youth through psychotropic medication monitoring checklists (Bruins et al., 2017; Ninan et al., 2014; Simoons et al., 2019). Clinicians practicing TAU rarely employ instruments to monitor treatment (Simoons et al., 2019; Wright et al., 2017). When used, instruments are more likely to be administered for medicolegal (i.e., early identification of tardive dyskinesia) or administrative reasons than for progress monitoring (Youngstrom & van Meter, 2018).

## General Instruments for Measuring Effects of Psychotropic Medication

General instruments monitor effects irrespective of medication class. Comprehensive reviews have found that an ideal instrument is not currently available for measuring psychotropic medication effects in persons with ASD (Anagnostou et al., 2015; Lecavalier et al., 2014; McConachie et al., 2015; Scahill et al., 2015). McConachie et al. (2015) reviewed 132 instruments identifying 41 tools with some positive evidence for use with children under six, with the Aberrant Behavior Checklist (ABC), Child Behavior Checklist (CBCL), and the Home Situations Questionnaire-Pervasive Developmental Disorders (HSQ-PDD) receiving high ratings. The ABC is widely used to measure treatment effects in persons with ID (Aman et al., 1985). The ABC can be used to measure the effects of medication and psychosocial interventions (Aman et al., 2004). The ABC has been shown to have structural, convergent, and divergent validity for monitoring target symptoms in persons with ASD (Kaat et al., 2014; Norris et al., 2019). The CBCL (Achenbach, 1966) has been used in thousands of studies in multiple settings (Achenbach et al., 2008). While useful in screening for behavioral challenges children with ASD/PDD, the CBCL yields a high rate of false positives when used as a screen for ASD (Havdahl et al., 2016). In addition, while item responses are useful in identifying target symptoms, the CBCL syndrome scales are less useful for children with ASD, with or without ID (Dovgan et al., 2019; Medeiros et al., 2017). The HSQ was developed by

**Table 1** Instruments measuring effects and side effects of psychotropic medication in persons with ASD and PDD

| Instrument (in order of appearance in chapter) | Description |
|---|---|
| Monitoring Outcomes of Psychiatric Psychopharmacology (MOPHAR) | A comprehensive psychotropic tracking scheme monitoring clinical, physical, and laboratory parameters |
| Aberrant Behavior Checklist (ABC) | A 58-item, treater- or carer-rated scale measuring irritability, social withdrawal, stereotypic behavior, hyperactivity/noncompliance, and inappropriate speech. It is widely used with adults and children |
| Child Behavior Checklist (CBCL) | A 113-item, carer-rated scale screening for anxiety, depression, somatic complaints, social problems, thought problems, attention problems, rule-breaking behavior, aggressive behavior. Widely used to identify internalizing and externalizing behaviors in children and adolescents with ASD and PDD |
| Home Situations Questionnaire for Autism Spectrum Disorder (HSQ-ASD) | A caregiver-rated scale measuring disruptive behaviors in children with autism in everyday settings. Contains two domains: social inflexibility and demand specificity |
| Diagnostic Assessment for the Severely Handicapped Scale I, II (DASH I, II) | A 84-item, carer-rated measure, with 13 subscales (anxiety, depression, mania, developmental disorder/autism, schizophrenia, stereotypies, self-injury, elimination, eating, sleep, sexual symptoms organic symptoms, and impulse control symptoms) screening for mental illness in persons with severe and profound ID |
| Psychiatric Assessment Schedule for Adults with a Developmental Disability (PAS-ADD) | A 25 item, comprehensive, semi-structured clinical interview screening for mental disorders (depression, anxiety and phobias, mania, obsessive-compulsive disorder, psychosis, and unspecified disorder including dementia) in persons with PDD. Adult, children/adolescent, and abbreviated (Mini PAS-ADD) formats are available |
| Clinical Global Impression Scale (CGI) | A clinician-rated instrument rating illness severity, improvement and therapeutic response on a 7-point scale |
| Brief Psychiatric Rating Scale (BPRS) | A prescriber-rated scale rating somatic concern, anxiety, emotional withdrawal, conceptual disorganization, guilt feelings, tension, mannerisms and posturing, grandiosity, depressive mood, hostility, suspiciousness, hallucinatory behavior, motor retardation, uncooperativeness, unusual though content, blunted affect, excitement, disorientation on a 7-point scale |
| Autism Impact Measure (AIM) | A 41-item, online caregiver-completed instrument assessing treatment efficacy for core symptoms of ASD |
| Autism Behavior Inventory (ABI) | An online, caregiver-completed measure assessing treatment efficacy over five domains: social communication, restrictive and repetitive behaviors, mental health, self-regulation, challenging behavior in children and adults |
| Emotion Dysregulation Inventory (EDI) | A 30-item, carer-completed measure to treatment efficacy targeting emotional distress and dysregulation |

(continued)

**Table 1** (continued)

| Instrument (in order of appearance in chapter) | Description |
|---|---|
| Matson Evaluation of Drug Side Effects Scale (MEDS) | A 93-item, carer-rated scale with nine domains, developed to assess side effects of psychotropic medications in adults with ID |
| Udvalg for Kliniske Undersøgelser Side Effect Rating Scale-ID (UKU-SERS-ID) | A 35-item, clinician-administered semi-structured interview measuring side effects of psychotropic medications, rated on a Likert scale from 0 (not present) to 3 (severe) in adults with ID |
| Systematic Assessment for Treatment of Emergent Events (SAFTEE). | These general and specific clinician 78-item inquiries systematically identify and monitor treatment emergent events in clinical trials |
| The Safety Monitoring Uniform Report Form (SMURF) | A clinician-rated, standardized inquiry based on the SAFTEE, measuring psychotropic side effects in children with ASD and capturing onset, duration, pattern, status, severity, contributing factors, and action(s) taken |
| PsyLog | A mobile application for monitoring 30 common side effects of psychotropic medications |
| Kiddie-Schedule for Affective Disorders and Schizophrenia (K-SADS) | A semi-structured interview used to diagnose psychiatric illnesses in children between six and 18 years of age |
| ADHD Rating Scale (ADHD-RS) | An 18-item, parent- and teacher-report scale used to screen for ADHD and monitor treatment response |
| Conners Continuous Performance Test (CPT) | A computerized assessment of attention used for diagnostic and treatment monitoring |
| The National Institute for Children's Health Quality (NICHQ) Vanderbilt Rating Scale | A 55-item, parent-, teacher- and clinician-rated scale used to screen for ADHD, oppositional behaviors, anxiety and depression in children. It monitors treatment effects and academic and social performance |
| Brown Executive Function/ Attention Scales | A clinician- or self- rated scale for assessing ADHD and monitoring treatment in persons over the age of three |
| AACAP Stimulant Monitoring Form | A 25-item, carer-completed side stimulant scale rating side effects and efficacy on a four-point Likert scale |
| Pittsburg Side Effect Rating Scale | A three-item, carer-completed used to measure side effects of medications used to treat ADHD in children |
| Barkley Side Effect Rating Scale (SERS) | A 17-point, carer-completed scale rating the side effects of stimulants on a 10-point Likert scale |
| Autism-Tics, ADHD and other Comorbidities Inventory (A-TAC) | A 119-item parent phone interview with items scored on a three-point scale, used to screen for ASD, ADHD, tic disorders, and learning disorders in children between the ages of nine and 12 years old |
| Yale Global Tic Severity Scale | A structured interview identifying the number, frequency, intensity and complexity of motor and phonic tics |
| Beck Depression Inventory-II (BDI-II) | A 21-item, patient-rated scale for measuring adult depressive symptoms on a 4-point Likert scale |

(continued)

**Table 1** (continued)

| Instrument (in order of appearance in chapter) | Description |
|---|---|
| Adult Self-Report (ASR) | A 126-item, self-report questionnaire for adults using a three-point scale to rate anxious/depressed symptoms, social withdrawal, somatic complaints, thought problems, attention problems, aggressive behavior, rule-breaking behavior, and intrusive behavior as well as adaptive functioning as part of the Achenbach System |
| Depression Anxiety Stress Scales (DASS) | A self-report, set of three 14-item scales measuring depression, anxiety and tension/stress |
| Children's Depression Inventory (CDI-2) | A multi-rater assessment for emotional and functional problems including the presence and severity of depressive symptoms in persons between the ages of seven and 17 years of age |
| Children's Depression Rating Scale (CDRS) | A parent-, child-, and teacher-report, 16-item instrument, used to measure the severity of depression in children 6–12 years of age. Most widely used scale in research trials for childhood depression |
| Children's Yale-Brown Obsessive-Compulsive Scale | A semi-structured interview measuring the severity of obsessive/compulsive symptoms in children and adolescents between ages six and 17. An adult form is available |
| Obsessive Compulsive Inventory-Revised (OCI-R) | An 18-item, self-report scale measuring symptoms of OCD on a five-point Likert scale |
| NIMH Global Assessment Compulsive Scale | A clinician-rated single item scale used to measure OCD symptom severity and treatment effect |
| Antidepressant Side-Effect Checklist (ASEC) | A self-report checklist, scored on a three-point Likert scale, assessing for 21 potential antidepressant side effects |
| The Frequency, Intensity, and Burden of Side-Effects Rating (FIBSER) | A self-rated, three-item measure rating the frequency, intensity, and burden of antidepressant side effects on a 7 point Likert scale |
| Toronto Side-Effect Scale (TSES) | A 32-item, clinician-administered scale rating central nervous system, gastrointestinal and sexual side effects for frequency and severity rated on five-point Likert scales with a calculated intensity score. Also tracks weight |
| The National Institute of Mental Health Life Chart Methodology (NIMH-LCM™) | A retrospective and prospective method for documenting the longitudinal course of depressive or bipolar disorders by tracking symptoms, treatment, treatment effect and life events |
| Clinical Monitoring Form (CMF) | A time-efficient, comprehensive tool to track current clinical status, medication compliance, medication side effects during treatment for mood disorders |
| Mood Disorder Questionnaire (MDQ) | A 15- item, self-report screen for bipolar disorder, also used to monitor the symptoms of mania and hypomania |
| The Lithium Side Effects Rating Scale | A self-report, 30-item instrument, to measure side effects of lithium |
| General Side Effects Scale | A 14-item scale rating the potential side effects of lithium on a 4-point scale. Widely used in research |

(continued)

**Table 1** (continued)

| Instrument (in order of appearance in chapter) | Description |
|---|---|
| Scale for Evaluation and Identification of Seizures, Epilepsy and Anticonvulsants Side Effects (SEIZES) | A 52-item scale for assessing the common side effects of anticonvulsant medications in 14 categories including potential hematologic, electrolyte, hepatic, weight, respiratory, gastric, dermatological, gait, affect and cognitive disturbances, hair change, tremor, sedation and drug-related dizziness |
| The Liverpool Adverse Events Profile (LAED) | A 19-item self-report measure for anticonvulsant side effects with screening questions for depression and anxiety |
| The Side-effects of AED Treatment (SIDAED) | A 46-item self-report measure capturing 10 categories of physical and psychiatric side effects of anticonvulsant medications rated for duration and severity on a four-point Likert scale |
| Brief Negative Symptom Scale (BNSS) | A 13-item, clinician-rated scale tracking treatment effects on the negative symptoms of schizophrenia |
| Brief Psychiatric Rating Scale (BPRS) | An 18-symptom, clinician-rated scale rating symptoms of schizophrenia from 1 (not present) to 7 (extremely severe) based on interview and observations. Widely used in research |
| Clinical Assessment Interview for Negative Symptoms (CAINS) | A 23-item, seven-point interview assessing negative symptoms of schizophrenia—asociality, avolition, anhedonia (consummatory and anticipatory), affective flattening, and alogia |
| Positive and Negative Syndrome Scale (PANSS) | A 30-item, clinician-rated scale identifying general psychopathology and the positive/negative symptoms of schizophrenia; rated on a seven-point scale |
| Psychotic Symptom Rating Scales (PSYRATS) | A semi-structured interview assessing the experience of hallucinations (11 items) and delusions (six items) |
| Scale for the Assessment of Negative Symptoms (SANS) | A 25-item, clinician-rated measure of the negative symptoms of schizophrenia with four domains—affective flattening or blunting, alogia, avolition-apathy, and anhedonia-asociality—rated on a six-point scale |
| Scale for the Assessment of Positive Symptoms (SAPS) | A 34-item, clinician-rated measure of the positive symptoms of schizophrenia with four domains- hallucinations, delusions, bizarre behavior, and positive formal thought disorder- rated on a six-point scale |
| Abnormal Involuntary Movement Scale (AIMS) | A 12-item, clinician-rated scale designed to assess for tardive dyskinesia and track changes over time |
| Antipsychotic Non-Neurological Side Effects (ANNSERS) | A 44-item, patient- or carer-rated screen for antipsychotic side effects that are NOT due to EPS (parkinsonism, akathisia, dystonia, tardive dyskinesia) |
| Antipsychotic Side-effect Checklist (ASC) | A 17-item, clinician-led interview screening for common antipsychotic side effects and subjective distress |
| Barnes Akathisia Rating Scale (BARS) | A 4-item rating of subjective and objective akathisia symptoms with global akathisia severity rated on a 0–5 scale |
| Dyskinesia Identification System: Condensed User Scale (DISCUS) | A 15-item, clinician-rated screen for tardive dyskinesia |

(continued)

**Table 1** (continued)

| Instrument (in order of appearance in chapter) | Description |
|---|---|
| Simpson-Angus Extrapyramidal Side Effects Scale (SAS) | A 10-item, clinician observation and physical evaluation rated on a 10-item scale with items rated 0–4 to screen for drug-induced parkinsonism |
| Systematic Monitoring of Adverse Events Related to Treatments (SMARTS) | A 12-item, patient/carer completed screen for side effects of antipsychotic medications |
| Bush-Francis Catatonia Rating Scale (BFCRS) | A 23-item, clinician-rated scale used to screen, diagnose, and track symptoms of catatonia |

Barkley and Edelbrock (1987) to measure the degree of noncompliant behavior exhibited by children in common situations. The Research Units for Pediatric Psychopharmacology (RUPP) of the Autism Network has modified and validated the HSQ as the HSQ-PDD (Chowdhury et al., 2010) which was expanded as the HSQ-ASD to better measure disruptive behaviors in children with autism (Chowdhury et al., 2015). The HSQ-ASD has been used in trials of guanfacine and cannabidiol (Aran et al., 2018; Swatzyna et al., 2017).

Most scales that measure the psychiatric symptoms of adults with ASD/PDD cross multiple diagnostic categories and target persons with comorbid ID. For persons with ASD\PDD but without comorbid ID, scales for typically developing (TD) adults are used. The ABC is widely used to measure treatment effects in adults with ASD/PDD and ID (Aman et al., 1985). The Diagnostic Assessment for the Severely Handicapped (DASH) was developed specifically for the assessment of mental illness in adults with severe and profound ID (Matson et al., 1991), with the DASH II showing the stability of psychopathology over time (Horovitz et al., 2011). The PAS-ADD (Moss et al., 1998) and the Mini PAS-ADD (Prosser et al., 1998) are useful screens for general psychopathology in persons with ID. Overall severity and improvement may be tracked using the Clinical Global Impression Scale (CGI) or the Brief Psychiatric Rating Scale (BPRS) (Guy 1976; Overall & Gorham, 1962). While well-established in the research literature and quick to administer, the CGI and the BPRS offer little patient-specific detail.

New measures have been developed to address the limitations of long-established measures in monitoring psychotropic medication effects in persons with ASD/PDD. The capacity for frequent, real-time monitoring of medication effects is a strength of the Autism Impact Measure (AIM) (Houghton et al., 2019; Kanne et al., 2014) and the Autism Behavior Inventory (ABI) (Bangerter et al., 2017). The AIM and the ABI are designed for carers to complete online. The AIM and ABI focus on the core symptoms of ASD. Mazefsky et al. (2018) applied the National Institute of Health Patient-Reported Outcomes Measurement Information System (PROMIS®) principles when developing the Emotion Dysregulation Inventory (EDI), a carer-completed questionnaire designed to identify emotional distress and regulation issues and monitor treatment response. Because available measures have limitations in monitoring the effects of medication, the Autism Speaks Autism Treatment

Network suggests an idiographic approach, instructing carers to track target symptoms based on frequency, severity, and duration, with notation of medication changes and life events. In the idiographic approach, frequency, duration, and severity of target symptoms are tracked using a Likert scale (Cole et al., 2012).

## General Instruments for Monitoring Medication Side Effects

The most commonly used general instruments for measuring side effects in research involving children with ASD employ a Likert scale (Coleman et al., 2019). General scales for monitoring medication side effects in adults with ID include the Matson Evaluation of Drug Side Effects Scale (Matson et al., 1998) and the Udvalg for Kliniske Undersøgelser Side Effect Rating Scale-ID (Tveter et al., 2016). The Systematic Assessment for Treatment of Emergent Events (SAFTEE) is a standardized inquiry procedure that was developed for side effect monitoring in psychotropic drug trials with adults (Levine & Schooler, 1984). The Safety Monitoring Uniform Report Form (SMURF) is a pediatric standardized inquiry procedure based on the SAFTEE (Greenhill et al., 2004). The SMURF has been used in numerous studies to measure side effects in children with autism (Capano et al., 2018; DeMayo et al., 2017; Lyon et al., 2009). The Monitoring Outcomes of Psychiatric Psychopharmacology (MOPHAR) program for adults provides a comprehensive tracking scheme, including the clinical, physical, and laboratory parameters, to monitor for medication side effects (Simoons et al., 2019). Technology, including the mobile application Psychlog, is increasingly being used to capture side effects in real-time (Kuzman et al., 2017).

## Monitoring Stimulant and Non-Stimulant Medications Prescribed to Treat ADHD

Attention deficit hyperactivity disorder (ADHD) is the most common mental disorder diagnosed in childhood, with an overall 7.5% prevalence (Thomas et al., 2015) and a prevalence of 28% to 83% among persons with ASD (Lee & Ousley, 2006; Simonoff et al., 2008). Ghanizadeh (2012) reported that 53.8% of children with PDD met criteria for ADHD based on the Schedule for Affective Disorders and Schizophrenia (K-SADS) assessment. In his sample of 68 children and adolescents, children with autism, Asperger's syndrome, Rett Syndrome, childhood disintegrative disorder, and PDD-NOS qualified for co-morbid ADHD at rates of 55.4%, 16.9%, 3.1%, 3.1%, and 21.5%, respectively. Although children with ASD are diagnosed with ADHD up to 11 times more often than their TD peers, they are less likely to receive adequate treatment and when they do, psychotropic medication response is often less robust and side effects are more common (Joshi et al., 2017; Mahajan et al., 2012).

## Instruments to Measure the Effects of Stimulants and Nonstimulants Prescribed for ADHD

With the publication of the *DSM 5*, an ADHD diagnosis was no longer precluded in children with ASD, stimulating research to better understand ADHD symptom profiles in children with ASD. The *DSM 5* diagnosis of ADHD requires clinical knowledge of the developmental trajectory of youth with ASD in order to determine if symptoms of hyperactivity, inattention, and impulsivity exceed those expected for a child's mental age (American Psychiatric Association & American Psychiatric Association *DSM-5* Task Force., 2013). Diagnostic and treatment monitoring are challenging for youth with ASD who have ADHD because inattention, concentration, and excessive movement may be due to ASD/PDD or ADHD, or a combination of these disorders. For youth who also have ID, an additional layer of complexity is added. Assigning the diagnosis of ADHD requires ruling out alternative explanations for inattention, impulsivity, or hyperactivity. The prescriber must consider whether each ADHD symptom could be due to ASD/PDD or ID. For example, fidgetiness may be due to sensory issues or repetitive movements. In establishing a baseline for the frequency and severity of ADHD symptoms, it is necessary to fully understand a child's unique trajectory for each symptom. An FBA, checklists, or scales can augment clinical judgement but are not standalone tools for the diagnosis of ADHD or medication effect and side-effect monitoring.

To date, the ADHD-RS shows the greatest promise for distinguishing between ASD and ADHD, but it is not without limitations (Rau et al., 2020; Yerys et al., 2017). Yerys et al. (2017) found that the ADHD-RS-IV did not adequately differentiate inattention from impulsivity\ hyperactivity and may result in a false positive diagnosis of ADHD in persons with ASD if core ASD symptoms are not taken into account. Rau et al. (2020) reported that the inattentive subscale rated by parent, but not teacher report, allowed differentiation between inattentive type ADHD and ASD. Lundervold et al. (2012) reported that the performance of children with ASD and ADHD on the Conner's Continuous Performance Test–II was more similar to children with ADHD than those with ASD without ADHD. The ABC was not designed to screen for ADHD, but does identify hyperactive and disruptive behaviors and is well-validated in children with ASD and ID (Kaat et al., 2014). While not validated for children with ASD/PDD, the Vanderbilt Rating Scale, Brown Rating Scales, and Conner's Rating Scale are commonly used to screen for ADHD and monitor treatment effect in clinical practice.

## Instruments to Measure the Side Effects of Stimulant

The AACAP has developed a Stimulant Monitoring Form for Children and Adolescents to monitor effects and side effects. In addition to attention, concentration, and hyperactivity, the form allows carers to track side effects and medication

compliance. The Pittsburg Side Effect Rating Scale (Pelham Jr, 1993) and the Barkley Side Effect Rating Scale (Barkley et al., 1990) have been widely used in research but have not been validated for children with ASD.

In addition to monitoring for side effects, blood pressure, pulse, weight, and height should be checked at each appointment. Persons with comorbid medical conditions may require additional monitoring. Tic disorders are common in persons with ADHD, with tics often becoming more frequent with medication treatment (Oluwabusi et al., 2016). The Autism-Tics, ADHD and Other Co-morbidities Inventory (Larson et al., 2010) and the Yale Global Tic Severity Scale (Leckman et al., 1989) have been used clinically and in research involving persons with autism (Martino et al., 2017). The nonstimulant, atomoxetine, carries a U.S. Food and Drug Administration black box warning for suicidal ideations in children and adolescents (Hamad, 2004). A systematic review conducted in 2019 found no suicide risk assessment tools validated for teens with ASD (Howe et al., 2020). While laboratory studies are not routinely indicated for the monitoring medications for ADHD, prescribers must consider person-specific needs due to the high incidence of co-morbidities and polypharmacy in persons with ASD/PDD. Prescribers should be aware that children with congenital heart disease have an increased risk for ASD, necessitating physical examination and possibly an EKG to screen for cardiac abnormalities (Tsao et al., 2017).

## Monitoring Antidepressant Medications Prescribed to Treat Depression or Anxiety

Persons with ASD/PDD are commonly prescribed antidepressant medications to treat depression or anxiety. While anxiety is more common in children with ASD, adolescents and adults experience a higher prevalence of depression (Medeiros et al., 2017). A cohort study of 1014 persons with ASD in Minnesota noted the cumulative incidence of depression and anxiety as 53.7% and 55.6%, compared to 30.9% and 24.7% in controls (Kirsch et al., 2020). A meta-analysis by Hudson et al. (2019) reported that the lifetime incidence of depression is four times more likely in persons with ASD compared to TD cohorts. Rett Syndrome has also been associated with increased depression and anxiety (Barnes et al., 2015; Hryniewiecka-Jaworska et al., 2016). Mehra et al. (2019) found that limited information is available regarding depression and anxiety in persons with childhood disintegrative disorder, but did note that anxiety was common at the onset of regression. While dozens of measures to monitor anxiety and depression are available, none are ideal for monitoring psychotropic effects in persons with ASD/PDD (Grondhuis & Aman, 2012; Lecavalier et al., 2014).

## Instruments to Measure Effects of Antidepressants

While not validated for persons with ASD/PDD, the Beck Depression Inventory-II (BDI-II), Patient Health Questionnaire-9 (PHQ-9) and Montgomery-Åsberg Depression Rating Scale (MADRAS) have been used to measure treatment outcomes for adults with depression and ASD without ID (Cassidy et al., 2018). Gotham et al. (2015) found the BDI-II and the Adult Self-Report promising in a small sample of 16–31 year-olds with ASD and noted the value of self-report measures in tracking symptoms of depression in persons with a verbal IQ greater than 70. The Syriopoulou-Delli et al. (2019) comprehensive review of instruments assessing anxiety in children with ASD recommended obtaining information from more than one informant using multiple assessment methods and cautioned prescribers to carefully select developmentally appropriate measures due to idiosyncratic anxiety presentation in children with ASD. The Depression Anxiety Stress Scales (Antony et al., 1998), Children's Depression Inventory, parent-rated version (Kovacs et al., 1977) and the Children's Depression Rating Scale (Poznanski & Mokros, 1996), have shown research utility but have not been validated for monitoring the clinical effects for individuals with ASD/PDD (Mazzone et al., 2013; Nah et al., 2018; Ozsivadjian et al., 2014).

Persons with ASD are at increased risk for the diagnosis of OCD (Meier et al., 2015) and children with OCD are at increased risk for ASD (Arildskov et al., 2016). The RUPP-AN has reported that the Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS) as modified for PDD is a reliable measure (Scahill et al., 2006). Wu et al. (2014) found that the CY-BOCS has satisfactory psychometric properties for youth with ASD aged 7–15 years. The Obsessive Compulsive Inventory-Revised (OCI-R) has shown suitable psychometric properties for use with adults with ASD (Cadman et al., 2015). The National Institutes of Mental Health Global Assessment Compulsive Score has also been used to measure treatment effects for persons with ASD and OCD (Bowen & Murshid, 2016).

## Instruments to Measure the Side Effects of Antidepressants

The few measures that have been developed targeting antidepressant side-effect monitoring include The Antidepressant Side-Effect Checklist (Uher et al., 2009), The Frequency, Intensity, and Burden of Side-Effects Rating (Wisniewski et al., 2006), and the Toronto Side-Effect Scale (Vanderkooy et al., 2002). While used in research and clinical settings, these measures have not been studied in persons with ASD. These measures should be interpreted with caution in persons with ASD, as many items listed as side effects are known to occur commonly in persons with ASD, including constipation, nausea, abdominal pain, insomnia, and agitation.

Persons with ASD are more likely to experience suicidal ideations and attempt suicide that the general population (Chen et al., 2017). Antidepressants carry a

U.S. Food and Drug Administration black box warning for suicidal ideations in children and adolescents (Hamad, 2004). The WHO has issued a consensus statement on antidepressant monitoring noting that while the "benefit of treatment appears to exceed the suicide risk" close monitoring for suicidal ideations is required (Dodd et al., 2018, p. 337). A systematic review conducted in 2019 found no suicide risk assessment tools validated for teens with ASD (Howe et al., 2020).

## Monitoring Mood Stabilizers Prescribed to Treat Bipolar Disorders

Bipolar disorder is more common among persons with ASD than those in the general population (Ghaziuddin & Ghaziuddin, 2020). Treatment typically includes a mood stabilizer and/or an antipsychotic medication [see below]. Mood stabilizers include lithium and select anticonvulsant medications. In addition to clinical monitoring, mood stabilizers require baseline and periodic laboratory monitoring studies. Prescribers should reference Volume 2 of this series for additional information on the laboratory monitoring of mood stabilizers.

## Instruments to Measure Effects of Mood Stabilizers

Monitoring tools for bipolar disorder validated for use in persons with ASD are not currently available. Widely used tools include the NIMH Life Chart Methodology (NIMH-LCM™) and the Clinical Monitoring Form (CMF) which were originally developed for research. Both are available in paper and digital formats, including applications for smartphones (Rajagopalan et al., 2017). The Mood Disorder Questionnaire (MDQ) has been validated for monitoring the symptoms of mania and hypomania in adults and adolescents (Hirschfeld, 2002; Wagner et al., 2006). In addition, Nicholas et al. (2015) identified 35 symptom and medication monitoring apps specific to bipolar disorder.

## Instruments to Measure Side Effects of Mood Stabilizers

The few scales that have been designed specifically to monitor the side effects of lithium or mood stabilizers are used primarily in research. The Lithium Side Effects Rating Scale (Haddad et al., 1999) and the General Side Effects Scale (Strickland et al., 1995) have been validated for lithium side-effect monitoring. Scales for anticonvulsant side effect monitoring include the Scale for Evaluation and Identification of Seizures, Epilepsy and Anticonvulsants Side Effects (SEIZES) (Matson et al.,

2005), The Liverpool Adverse Events Profile (Baker, 1993), and the Side-effects of Antiepileptic Drug (Uijl et al., 2006). The SEIZES was developed for persons with developmental disability. Available scales have not been validated for persons with ASD.

## Monitoring Antipsychotic Medications Prescribed to Treat Psychotic Disorders

A meta-analysis of the prevalence of schizophrenia in persons with ASD without ID found a pooled prevalence of 6% compared to 2.5% in the general population (Marín et al., 2018; Saha et al., 2007; Saha et al., 2005). For children with schizophrenia, 30% to 50% have comorbid ASD/PDD (Rapoport et al., 2009). Not only are persons with ASD at greater risk for schizophrenia, they are also at greater risk of side effects from the medications used to treat these conditions. A systematic review and meta-analysis of over 50 studies addressing the side effects of persons with ASD receiving antipsychotic medications found a 50.5% pooled prevalence of side effects, with increased appetite and weight gain the most common (Alfageh et al., 2019). In a retrospective cohort study of 189,361 children, Ray et al. (2019) found a 3.5-fold increased risk of unexpected death among children who received antipsychotic doses greater than 50 mg chlorpromazine dose equivalents. Monitoring the effects and side effects of antipsychotic medications and mood stabilizers promotes treatment with the lowest possible dose of medication which minimizes risk for side effects.

## Instruments to Measure Antipsychotic Effects

While there is no shortage of psychometric instruments to measure the effects of antipsychotics, only a few have been validated for persons with ASD/PDD. Instruments commonly used to measure antipsychotic effects clinically and in research include the Brief Negative Symptom Scale (Kirkpatrick et al., 2010), the Brief Psychiatric Rating Scale (BPRS) (Overall & Gorham, 1962), Clinical Assessment Interview for Negative Symptoms (Forbes et al., 2010), Positive and Negative Syndrome Scale (PANSS) (Kay et al., 1987), Psychotic Symptom Rating Scales (PSYRATS) (Haddock et al., 1999), Scale for the Assessment of Negative Symptoms (SANS) (Andreasen, 1984), and the Scale for the Assessment of Positive Symptoms (SAPS) (Andreasen, 1984). The BPRS, PANSS, PSYRATS, SANS, and SAPS have been used in research involving persons with autism or ID. Only PANSS and PSYRATS have been shown to have validity and reliability for this purpose. The PANSS negative symptoms and the PSYRATS delusions subscales did not discriminate between adults with mild ID and psychosis, other mental illness, or no

mental illness (Hatton et al., 2005; Kästner et al., 2015). Total PANSS scores have clinical utility in comparing the effect of different antipsychotics in persons with comorbid ASD and schizophrenia (Barnard et al., 2002; Reddy et al., 2013). Symptoms of autism that also occur in schizophrenia include restricted expression of emotion, socialization difficulties, odd speech patterns, and difficulty with abstract thinking (De Crescenzo et al., 2019). Because autism and schizophrenia share symptoms and genetics, the negative symptom scale of the PANSS has been adapted to allow the differentiation of autism and schizophrenia as the PANSS Autism Severity Score (PAUSS) (Kästner et al., 2015).

## Instruments to Measure Antipsychotic Side Effects

The instruments used to monitor the side effects of antipsychotic medications are the most widely used in clinical practice and inform treatment of those receiving antipsychotics and who often have impaired thinking, which itself may limit self-observation and side-effects reporting. Antipsychotic medications pose the risk of serious movement disorders or extrapyramidal effects, including tardive dyskinesia (TD), akathisia, and dystonia. Comprehensive reviews of the instruments used to measure antipsychotic medication side effects in general populations have identified more than 50 in common use and note the need for additional psychometric studies (Stomski et al., 2015; van Strien et al., 2015). The Abnormal Involuntary Movement Scale (AIMS), Antipsychotic Non-Neurological Side Effects Rating Scale (ANNSERS), Antipsychotic Side-effect Checklist, Barnes Akathesia Rating Scale, Dyskinesia Identification System: Condensed User Scale, and Simpson-Angus Extrapyramidal Side Effects Scale are widely used in persons with ASD.

Arguably the most widely used in clinical practice, the Abnormal Involuntary Movement Scale (AIMS) is a clinician-rated scale, combined with a focused physical exam and designed to test for TD and to track changes over time (M. G. Aman et al., 2005; Magulac et al., 1999; Malone et al., 2002). The AIMS records involuntary abnormal body movements by severity from zero (none) to four (severe), with a total AIMS score of two or higher indicative of TD (Nagaraj et al., 2006). The DISCUS is a clinician-rated screen for TD which is valid and reliable for screening persons with ID (Lewis & Bodfish, 1998; Matson & Hess, 2011; Sprague & Kalachnik, 1991). In a review of side effect studies involving antipsychotic medication prescribed to individuals with ID, Matson and Mahan (2010a, 2010b) found that the DISCUS captured a significant increase in the levels of TD upon antipsychotic drug withdrawal. The DISCUS has also been used to measure levels of TD among adults with ID taking antipsychotics as compared to a no-medication group, with levels of TD higher among the medicated group (Matson et al., 2010). The DISCUS and the AIMS have also been used to assess side effects in persons with ASD (Aman et al., 2005). Checklists, such as the Systematic Monitoring of Adverse Events Related to Treatments (SMARTS), have been developed for side effect monitoring but have not been validated for use in persons with ASD/PDD (Haddad et al., 2014). As stereotyped or repetitive

movements are common in persons with ASD/PDD, a video recording is valuable for capturing any movements present at baseline and monitoring changes over time. In addition to screening for abnormal movements, persons receiving antipsychotic medication require baseline and periodic physical and laboratory monitoring. Commonly recommended parameters include baseline weight, waist circumference, blood pressure, pulse, EKG, fasting blood glucose, glycosylated hemoglobin (HbA1c), lipid profile, prolactin level, assessment of nutritional status, and level of physical activity, with regular follow-up monitoring of vital signs and for extrapyramidal side effects (EPS) and/or metabolic syndrome (NICE, 2017).

Medications, including antipsychotics, lithium, disulfiram, azithromycin, and GHB have been associated with catatonia (Oldham, 2018). The *DSM-5* (2013) defines catatonia as "a marked psychomotor disturbance that may involve decreased motor activity, decreased engagement, or excessive and peculiar motor activity" (p. 119). Persons with developmental disorders are at increased risk of developing catatonia, with a reported incidence of 31% (Consoli et al., 2012) compared to 9% in general populations (Solmi et al., 2017). The diagnosis of catatonia is challenging because symptoms can change over time. Rating scales and video recordings should be used at baseline and to monitor the treatment of catatonia (Sienaert et al., 2011). The Bush-Francis Catatonia Rating Scale (BFCRS) is the most commonly used instrument (Bush et al., 1996).

## Future Directions

While pharmacokinetics or pharmacogenetic testing may be indicated in some persons, additional research is necessary to better understand how these measures may best be implemented for persons with ASD/PDD (Bousman et al., 2019). Personalized medicine, also called precision or genomic medicine, holds promise for maximizing effect and minimizing side effects with the use of biomarker informed pharmacological treatment (Frye et al., 2019; Stern et al., 2018). The Analysis of Establishing Moderators and Biosignatures of Antidepressant Response in Clinical Care data suggests the utility of EEG-based network functional connectivity analysis in predicting medication response (Rolle et al., 2020), but additional study is needed before EEG-guided treatment becomes routine.

Technology holds the promise of streamlining instrument administration and analysis to further the practice of precision medicine in integrating an individual's biology, environment, and lifestyle to inform treatment (Arnett et al., 2019; Geschwind & State, 2015). For example, Dajani et al. (2016) have reported distinct patterns of executive functioning in typically developing children with ADHD, children with ADHD and ASD, and those with ASD, highlighting the importance of interventions targeted to specific patient needs. Precision therapies for the core symptoms and mental illness experienced by persons with ASD/PDD will allow treatment targeted to individual needs, rather than attempting to address the diverse presentations of persons with ASD/PDD with a single approach.

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